BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

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| In the matter of the adoption of New Rule I and the amendment of ARM 37.5.117, 37.5.304, 37.5.325, 37.86.1101, and 37.86.1102 pertaining to establishing hearings for disputes related to the Medicaid Drug Rebate program | ) ) ) ) ) ) ) | NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION AND AMENDMENT |

TO: All Concerned Persons

1. On November 26, 2008, at 10:30 a.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed adoption and amendment of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact Department of Public Health and Human Services no later than 5:00 p.m. on November 17, 2008, to advise us of the nature of the accommodation that you need. Please contact Rhonda Lesofski, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena MT 59604-4210; telephone (406) 444-4094; fax (406) 444-1970; or e-mail dphhslegal@mt.gov.

3. The rule as proposed to be adopted provides as follows:

RULE I OPPORTUNITY FOR HEARING (1) In any quarter in which a discrepancy in Medicaid utilization information is discovered by the manufacturer, which the manufacturer and the department are unable to resolve, the manufacturer will provide written notice of the discrepancy, by NDC number, to the department prior to the due date specified in ARM 37.86.1102.

(2) If the manufacturer asserts the department's Medicaid utilization information is erroneous, the manufacturer shall pay the department that portion of the rebate amount that is not disputed by the required due date in ARM 37.86.1102. The balance due, if any, plus a reasonable rate of interest as set forth in 42 USC 1396b(d)(5)(2008), will be paid or credited by the manufacturer or the department by the due date of the next quarterly payment in ARM 37.86.1102(8) after resolution of the dispute.

(3) Adjustments to rebate payments shall be made if information indicates that either Medicaid utilization information, Average Manufacturer Price (AMP), or Best Price were greater or less than the amount previously specified.

(4) The department and the manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of disputes noted by the manufacturer in ARM 37.86.1102. In the event that the department and the manufacturer are not able to resolve a discrepancy within 60 days, the department shall make available to the manufacturer the department's hearing mechanism as set forth in Title 37, chapter 5, subchapter 3.

AUTH: 53-6-113, MCA
IMP: 53-6-6-101, MCA

4. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.5.117 CERTAIN TITLE 50 PROGRAMS AND OTHER PROGRAMS FOR WHICH NO PROCEDURE IS OTHERWISE SPECIFIED: APPLICABLE HEARING PROCEDURES (1) Hearings under the programs specified in ~~(1)(a) through (1)(u)~~ this rule are available to the extent specifically provided by law, including the Montana Code Annotated and department rules. The provisions of ARM 37.5.311 and 37.5.318 do not apply to such hearings. Such hearings shall be conducted in accordance with the Montana Administrative Procedure Act and ARM 37.5.304, 37.5.307, 37.5.313, 37.5.316, 37.5.322, 37.5.325, 37.5.328, 37.5.331, 37.5.334, and 37.5.337.

(a) through (s) remain the same.

(t) denial or other determinations of the amount, duration, or continuation of an adoption subsidy under ARM Title 37, chapter 52, subchapter 2; ~~and~~

(u) requests for review of determinations by the department regarding pharmaceutical manufacturer's rebate agreements pursuant to ARM 37.86.1102; and

~~(u)~~ (v) any department program with respect to which a right to hearing is specifically granted by law, including department rule, but for which a hearing process is not otherwise provided by department rule.

AUTH: 50-1-202, 53-2-201, 53-6-113, MCA
IMP: 41-3-1103, 41-3-1142, 42-10-104, 50-1-202, 50-4-612, 50-5-103, 50-6-103, 50-6-402, 50-15-102, 50-15-103, 50-15-121, 50-15-122, 50-31-104, 50-52-102, 50-53-103, 52-2-111, 53-2-201, 53-4-1004, 53-6-101, 53-6-111, 53-6-113, 53-6-402, 53-20-305, 53-24-208, MCA

37.5.304 DEFINITIONS For purposes of this subchapter, unless the context requires otherwise, the following definitions apply:

(1) "Adverse action" means:

(a) through (d) remain the same.

(e) an action by the department to deny, terminate, or fail to renew certification or a provider agreement for the Medicaid program to any nursing facility or intermediate care facility for the mentally retarded;

(f) an action by the department to deny, suspend, reduce, revoke, or terminate licensure, registration, certification, or enrollment of a provider or to fail to

renew certification, enrollment, licensure, or the registration certificate of a provider who has applied for renewal;

(g) through (l) remain the same.

(m) an action by the department denying or reducing a special needs adjustment as provided in ARM 37.80.205; ~~or~~

(n) a department's substantiation determination of a report of child abuse, neglect, or exploitation under ARM Title 37, chapter 47, subchapter 6~~.~~; or

(o) a determination by the department regarding a pharmaceutical manufacturer's rebate due under ARM Title 37, chapter 86, subchapter 11.

(2) through (12)(d) remain the same.

AUTH: 2-4-201, 41-3-208, 41-3-1142, 52-2-111, 52-2-112, 52-2-403, 52-2-704, 52-3-304, 52-3-804, 53-2-201, 53-2-606, 53-2-803, 53-3-102, 53-3-107, 53-4-111, 53-4-212, 53-4-403, 53-4-503, 53-5-304, 53-5-504, 53-6-111, 53-6-113, 53-7-102, 53-20-305, MCA
IMP: 2-4-201, 41-3-202, 41-3-208, 41-3-1103, 52-2-704, 52-2-726, 53-2-201, 53-2-306, 53-2-606, 53-2-801, 53-3-107, 53-4-112, 53-4-404, 53-4-503, 53-4-513, 53-5-304, 53-6-101, 53-6-111, 53-6-113, 53-20-305, MCA

37.5.325 HEARING PROCEDURE (1) through (2) remain the same.

(3) Hearings for medical assistance providers and for pharmaceutical manufacturers under Title 37, chapter 86, subchapter 11, shall be held at Helena, Montana and shall be in person except that the hearing may be conducted by telephone as mutually agreed by the parties. The department may designate the place of hearing either by notifying the Office of Fair Hearings in writing that hearings in a particular program will generally be held in a particular place or by designating the place of hearing on a case by case basis.

(4) The hearing officer shall notify the claimant or provider or his authorized representative by certified mail at least ten days in advance of the time and place of the hearing. The claimant or provider may waive in writing the right to ten days notice.

(a) The notice of hearing shall include:

(i) through (iii) remain the same.

(iv) an explanation of claimant's or provider's rights as enumerated in ~~(5) of~~ this rule; and

(v) remains the same.

(5) The claimant or provider shall have adequate opportunity:

(a) to examine the contents of his case file, except for those portions which the claimant is precluded from examining by state or federal law or regulation or directive of a medical professional, and all documents, and records to be used by the department at the hearing at a reasonable time prior to the hearing as well as during the hearing. Portions of the case file, documents, and records that the claimant is not allowed to examine are not admissible as evidence at the hearing;

(b) through (f) remain the same.

(6) Discovery shall be available to the parties. The department ~~hereby~~ adopts and incorporates by reference the Attorney General's Model Rule ~~13 found in~~ ARM 1.3.217 which sets forth the procedures for discovery in contested cases. A

copy of the model rule may be obtained by contacting either the Attorney General's Office, 215 North Sanders, P.O. Box 201401, Helena, MT 59620-1401 or Department of Public Health and Human Services, Office of Legal Affairs, 111 N. Sanders, P.O. Box 4210, Helena, MT 59604-4210.

AUTH: 2-4-201, 53-2-201, 53-2-206, 53-4-212, 53-6-113, 53-7-102, MCA
IMP: 2-4-602, 53-2-201, 53-6-101, MCA

37.86.1101 OUTPATIENT DRUGS, DEFINITIONS (1) "Average manufacturer price (AMP)" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. The AMP is determined without regard to customary prompt pay discounts extended to wholesalers.

(2) "Best price" means with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under an approved new drug application) the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.

~~(1)~~ (3) "Estimated acquisition cost (EAC)" means the cost of drugs for which no maximum allowable cost (MAC) price has been determined. The EAC is the department's best estimate of what price providers are generally paying in the state for a drug in the package size providers buy most frequently. The EAC for a drug is:

(a) and (b) remain the same.

(c) the department may set an allowable acquisition cost for specified drugs or drug categories when the department determines that acquisition cost is lower than ~~(1)(a)~~ (3)(a) or (b) based on data provided by the drug pricing file contractor.

(2) through (5) remain the same but are renumbered (4) through (7).

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-2-201, 53-6-101, 53-6-111, 53-6-113, MCA

37.86.1102 OUTPATIENT DRUGS, REQUIREMENTS (1) and (2) remain the same.

(3) The department will only participate in the payment of legend and over the counter drugs listed on the department drug formulary, as determined by the Medicaid Drug Formulary Committee established by the department. The formulary committee is the Drug Use Review Board, established and operating in accordance with 42 USC 1396r-8 ~~(2004)~~ (2008), which governs Medicaid drug programs. The drug formulary includes a preferred drug list (PDL) of selected drugs that have a significant clinical benefit over other agents in the same therapeutic class and also represents good value to the department based on total cost. Prescribers must prescribe from the preferred drug list if medically appropriate.

(a) through (5)(b) remain the same.

(6) The department will not participate in the payment of a prescription drug:

(a) remains the same.

(b) that is not subject to a rebate agreement between the manufacturer and the secretary of HHS as required by 42 USC 1396r-8 ~~(2004)~~ (2008); and

(c) that does not meet prior authorization criteria as determined by the Medicaid Drug Formulary Committee, established and operating in accordance with 42 USC 1396r-8 ~~(2004)~~ (2008), without the existence of a prior authorization request approved by the department or its designated representative. A list of drugs subject to prior authorization, known as the prior authorization drug list, will be provided to interested Medicaid providers.

(7) The drug formulary, PDL, and the prior authorization drug list will be updated by the department on a monthly basis, on the last day of each month. A copy of the most current listings may be obtained from the department web site at ~~www.dphhs.state.mt.us~~ www.dphhs.mt.gov, or by writing to the Department of Public Health and Human Services, Health Resources Division, Acute Services Bureau, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(8) ~~The department hereby adopts and incorporates by reference 42 USC 1396r-8 (2004) as a part of these rules. This section of the federal law sets forth the requirements that must be met by the department, drug manufacturers, and providers in order to receive reimbursement for outpatient drugs that have been dispensed. This statute describes rebate agreements, covered drugs, prior authorization, reimbursement limits, and drug use review programs. A copy of 42 USC 1396r-8 (2004) can be obtained by writing to the Department of Public Health and Human Services, Health Resources Division, Acute Services Bureau, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.~~ The department has a drug rebate program administered in accordance with 42 USC 1396r-8 (2008) and CMS state releases, CMS drug manufacturer releases, and the National Drug Rebate Agreement in effect in 2008, which the department adopts and incorporates by reference. A copy of all documents incorporated by reference in this rule may be obtained from the department web site at www.dphhs.mt.gov, or by writing to the Department of Public Health and Human Services, Health Resources Division, Acute Services Bureau, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(a) Pharmaceutical manufacturers, hereafter referred to as the manufacturer, will make rebate payments to the department for each calendar quarter within 30 days after receiving from the department the Medicaid utilization information defined in their federal rebate agreement. The manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(b) 42 USC 1396r-8 (2008) states the requirements that must be met by the department, drug manufacturers, and providers to receive reimbursement for outpatient drugs that have been dispensed. This statute describes rebate agreements, covered drugs, prior authorization, reimbursement limits, and drug use review programs.

(9) through (10)(f) remain the same.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-2-201, 53-6-101, 53-6-113, 53-6-141, MCA

5. The Department of Public Health and Human Services, Health Resource Division (the department) administers the Montana Medicaid program, which provides medical assistance to qualified low income and disabled residents of Montana. The program includes a pharmacy benefit. The state of Montana and the federal government jointly fund the Montana Medicaid program, including the pharmacy benefit. Section 53-6-113(2), MCA, requires the department to provide Medicaid services in a cost effective manner. The department and the federal government attempt to control pharmaceutical costs in a number of ways, including requiring rebates from drug manufacturers.

The Drug Rebate program is administered by the department in compliance with 42 USC1396r-8 and the Center for Medicare and Medicaid Services' (CMS ) state releases, and drug manufacturer releases, and the national drug rebate agreement.

The Montana Medicaid program is subject to federal review by the federal Department of Health and Human Services (HHS), Office of Inspector General (OIG). During a recent OIG review of the Medicaid drug rebate program the federal government required that the department provide an administrative hearing process for pharmaceutical manufacturers. The HHS OIG report states: "Furthermore, we also continue to recommend that the state agency develop and follow policies and procedures that include: actively pursuing disputed drug rebates including utilization of the state agency's hearing mechanism."

The department accepts the OIG recommendation and these proposed rule changes are reasonably necessary to implement those recommendations.

RULE I

This rule is being proposed to provide an informal and formal process for pharmaceutical manufacturers to dispute Medicaid utilization information used to calculate the rebate amounts due from a manufacturer to the Medicaid program. The department has successfully resolved disputes related to the drug rebate program since 1991 but a formal procedure is necessary to comply with federal guidelines.

ARM 37.5.117

This rule lists the programs that the department administers that do not have a specific, statutorily mandated opportunity for a hearing but a hearing is available to the extent provided by law or rule. The rule is being amended to list hearings for pharmaceutical manufacturers for disputes arising under ARM 37.86.1102 as a hearing available pursuant to department rule.

ARM 37.5.304

State law or department rule provides the opportunity for hearing on a broad variety of programs administered by the department. This rule defines terms used in the department's procedural rules implementing procedures for these hearings. The term "adverse action" is used to describe a number of department actions that may be appealed. This rule is being amended to include a determination by the department regarding a pharmaceutical manufacturer's rebate in the list of department adverse action that may be appealed. This amendment has the effect of establishing the procedures applicable to a hearing on disputes related to Medicaid drug rebates.

ARM 37.5.325

This rule establishes where hearings may be held and states notice requirements. The typical hearing on an adverse action of the department is held in the county seat of the claimant's residence. Drug rebate disputes would involve pharmaceutical manufacturers that do not have a county of residence in Montana. This rule is being amended to provide that hearings on drug rebate matters would be held in Helena, Montana.

ARM 37.86.1101

Definitions of the terms "Average Manufacturer price" and "Best Price" are added to this definition rule. There is no change in how the department defines these terms. It is adding the definitions for reader clarity.

ARM 37.86.1102

The Medicaid drug coverage benefit includes a formulary drug rebate program established by federal law in 1991. (The Omnibus Budget Reconciliation Act of 1990.) Drug manufacturers who want their drugs covered under state Medicaid programs must have a national rebate agreement with the federal Department of Health and Human Services (HHS). The drug rebate program is administered by HHS' Centers for Medicare and Medicaid Services.

ARM 37.86.1102 was adopted to implement provisions of the Montana Medicaid drug coverage benefit for Medicaid recipients. The department administers the benefit, in part, by adopting by reference federal guidance and requirements related to covered drugs, a drug formulary, a drug use review board, prior authorization, and a rebate program. This rule is being amended to adopt by reference current federal material.

Alternative considered

The department considered the merits of HHS' OIG audit recommendations and considered the alternative of taking no action.

Fiscal Effects

MAR Notice No. 37-458

This rule amendment will cost the department $0.

Persons and entities affected

This rule impacts zero providers and 500 pharmaceutical manufacturers.

6. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Rhonda Lesofski, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena MT 59604-4210; telephone (406) 444-4094; fax (406) 444-1970; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., December 4, 2008.

7. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

8. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 6 above or may be made by completing a request form at any rules hearing held by the department.

9. An electronic copy of this Proposal Notice is available through the Secretary of State's web site at http://sos.mt.gov/ARM/Register. The Secretary of State strives to make the electronic copy of the Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.

10. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

11. The department intends for the proposed adoption and amendment of these rules to be effective January 1, 2009.

/s/ Geralyn Driscoll
Rule Reviewer

/s/ Russell E. Cater for
Joan Miles, Director
Public Health and Human Services

Certified to the Secretary of State October 27, 2008.

MAR Notice No. 37-458